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Chairman Davis and Members of the Committee on Government Reform, I thank you for the opportunity to testify today. I have been asked to address issues related to the impact of pharmaceutical promotions on physician prescribing and the quality and cost of health care from my perspective as a medical school dean, an educator, a medical researcher, and a former medical journal editor.

Pharmaceutical expenditures are the fastest growing part of health care costs increasing at 15% a year. Americans spend 8% their health care dollars on drugs – much of this coming out of their own pockets. A conservative estimate is that last year Pharma spent \$20 billion dollars on drug marketing and promotion or as Pharma prefers to call it “educational outreach”. During this same time period all the US medical schools spent only \$3.5 on medical education and residencies spent \$3.9 billion on education (calculations based on demographic data provided in personal communication AAMC). This \$20 billion is far more than is spent on research and development, and is more than is spent on manufacturing and distribution. Promotional (marketing) money is divided between promoting drug products to physicians and promoting the same products to the public. Most of the following presentation will focus on physician-Pharma interactions but DTC advertising is not to be overlooked as an enormous source of misleading information that results in inappropriate medical care with a huge impact on medical costs, patient expectations, and iatrogenic illness.

### **How do doctors learn about new drugs?**

In an ideal world medical schools would teach students to make prescribing decisions based on the best available evidence taking in to account benefits, risks, costs, and mechanisms of action. In fact, medical schools spend shockingly little time teaching doctors in training about rational prescribing. In four years of medical school, less than 5% of actual teaching time relates to the use of medications. Once a doctor completes her training there is no formal, independent system to teach doctors about new drugs and treatments. It is catch as catch can. This is where Pharma has stepped in. Not surprisingly, the prescribing practices of most physicians and physicians in training are heavily influenced by \$20 billion spent on drug promotion.

The end result of Pharma’s major role in educating doctors about prescription drugs is poor, dangerous, and overly expensive prescribing practices of American physicians. There are example after example of where, despite sound evidence, doctors write prescriptions for inferior but heavily marketed products (beta blockers, finasteride, diabetes drugs, fluoroquinolones, calcium channel blocking drugs, dementia drugs, TPA, etc.) ignoring or being unaware of the scientific evidence.

### **How effective are physician – drug rep interactions**

In chemistry class when we study chemical reactions the step, in a multistep reaction, that limits the speed of the reaction is called the “rate-limiting step”. In

medicine, the rate-limiting step leading to increased drugs sales is the doctor who, after all, writes the prescription. Pharma currently employs an army of 88,000 sales reps who are on the front lines with doctors convincing them to write prescriptions for expensive drugs, occasionally dangerous drugs, and often drugs that are far less effective than alternatives. There is one drug rep for every six physicians or thought of in economic terms Pharma spends about \$9000 per doctor per year. Perhaps more appropriate for Congressional consideration is whether prescription drug costs would be substantially lower if we did away with this costly promotion. Lower drug costs would almost certainly translate in to more people getting the drugs they really need.

Drug reps (detailers) are usually gregarious, young, and attractive. And they are well schooled in persuasion. Written manuals, videos, and simulation exercises are just a few of the trench warfare tools used to teach detailers how to engage doctors in the field. Detailers are usually found roaming hospital hallways or paying visits to doctors' offices. Dressed in their conservative business attire they almost always come with gifts including free samples, flowers for the front office staff (who are crucial in helping to arrange for the doctor to meet the rep), lunches, books, loads of pens, and invitations to dinners, sporting events and trips. There are even examples of drug companies actually paying doctors to prescribe their drug.

As a child, my mother told me I couldn't buy anything advertised on TV. She explained that if the product was really that good the manufacturer wouldn't need to spend all that money telling everyone how good it was. The same is true for drugs. Very few drugs being advertised are any great shakes. In fact, most medical professors tell our students to avoid prescribing any new drugs until its use can be tested and established in the real world of medical practice as opposed to pharmaceutically sponsored drug studies. Advertising is meant to sell drugs and the less effective the drug the more marketing it takes to sell it.

### **Why should drug promotion be different from car promotion?**

When a bright person decides to purchase a car they shop around, they read Consumer's Report, and they talk to the car salesman. The consumer decides what size engine, what color, and what model they want. Short of lying or being fraudulent the car salesman is there to sell cars and the buyer must beware. No one expects a car salesman to act in the public's interest – they are only there to sell cars.

As a profession, medicine is profoundly different. We have a covenant with society to act in society's best interest. Doctors go to school for years to learn their science. And we use that science for the public's benefit. We interpret and explain the risks and benefits of a treatment so that a sick person can decide what course of action they wish to take. The patient needs the doctor solidly in their corner.

In exchange for all this hard work and for acting selflessly, doctors are given lots of privileges. Doctors are paid handsomely, they have all the rights of a profession including deciding who gets in to the profession and who can call themselves doctors.

But once we let our own self-interest get in the way we break our covenant with society and we invite public outrage and oversight. All these gifts, trips, tickets, and lunches have compromised the public's trust.

### **How accurate is the information provided by Pharma to doctors?**

First, one has to decide what standard should be applied to promotional information. If they are "just ads", then perhaps they should be held to no higher standard than the promotional material for Volvos, Coke, or Crest toothpaste. If, as is maintained by Pharma, their material is "educational" then their ads need to be held to the high standards of educational material that usually includes peer review, high factual accuracy, and clarity.

In fact, promotional material is not meeting these standards. As Former FDA Commissioner Kessler described, "...enormous potential exists for misleading advertisements to reach the physician and influence prescribing decisions...misleading advertisements can result in significant adverse consequences...needless injury or even death may occur because physicians have been persuaded to prescribe products for uses for which they have not been adequately tested or to substitute therapies that may be less safe or less effective than the alternatives.

Stryer and Bero showed that much information (42%) failed to comply with one or more FDA regulation including 35%, which lacked fair balance between risks and benefits. My research has shown that 40% of print ads in medical journals did not present fair balance, 58% contained images that expert reviewers felt minimized concerns about side effects, and that 47% of the ads did not appropriately highlight risks and contraindications in special populations such as the elderly. Few ads addressed cost. Collectively, these research findings are typical of this body of literature.

### **What impact does pharmaceutical promotion have on doctors' knowledge?**

Studies, including several that I have conducted, show that lots of promotional material contains inaccuracies, or at least presents very selective accounts of the evidence about the drug. Do these inaccuracies impact on patient's health?

Traditionally doctors report using three sources of information to find out about new drugs -- materials from sales representatives, CME conferences, and journal advertisements. How these sources are used depends upon the specialty of the physician and on the age of the doctor. Those in practice more than 15 years tend to rely more heavily on drug sales representatives as a source of information about new drugs while more recent grads tend to rely on CME courses. Several reports suggest that drug promotional material is often used as a primary source of information for new drugs, especially for conditions for which the doctor is uncertain. These are precisely the conditions when we would want our doctor reading a reliable source or talking with an expert (pharmacist).

## Doesn't it make sense for doctors to learn directly from the pharmaceutical industry?

There is no question that doctors are inadequately trained to use medications. Most medical schools under teach clinical pharmacology, and more importantly, few of us teach medical students or residents how to appropriately use the expertise of pharmacists.

From a pharmaceutical manufacturer's perspective *education* is about teaching the "clinically naive" how to start using your outstandingly beneficial product. Such activities are not educational in the slightest. They are pure promotion and in fact the funds for this "education" come from the companies' *marketing budgets*. This is contrary to how medical schools teach our trainees. The mantra in medical education is "evidence based curriculum" – in other words teach what the independent, non biased studies actually show about a drugs effectiveness when compared to the most commonly used alternative drugs. Medical educators are working to revise and update our teaching.

But educating the huge number of practicing physicians is far more difficult. Continuing Medical Education (CME) is a requirement for doctors in nearly all states. This is because medicine is not a fixed science but an evolving art. New knowledge quickly supplants old and doctors, who would otherwise choose to see more patients, are often hesitant to take time off to study and learn new material. CME has become an important part of doctors' professional lives and Pharma money has become the life-line of CME. As every editor of a medical journal knows, and most providers of CME know, doctors are hesitant – some might say unwilling – to pay a fee for quality learning material. This is why journals are dependent upon advertising revenue and why professional societies such as the AMA, the American College of Physicians, Society for Critical Care Medicine and the Thyroid Society are all beholden to drug companies. The recent prestigious American College of Physicians (ACP) annual meeting had nearly every event and every possible minute underwritten by Pharma. In fact, in contrast to their written ethical standards they chose to promote themselves to drug companies with the following claim, "...an unparalleled opportunity to meet physicians with power...prescribing power".

The medical profession and Pharma have an unhealthy symbiotic relationship that is pulling down the medical profession. The professional groups provide the doctors and the drug companies provide the money. Medical journals, medical societies, and even medical schools fight to woo drug company sponsorship of educational events. Without their sponsorship CME activities would be more basic, less high-tech, and perhaps it would cost a bit more to attend but they would be honest, accurate, and trustworthy.

Pharma maintains it is providing an "educational service" – even though Pharma provides the food, the speakers, the slides, and the agenda. But it takes two to tango and the medical profession – particularly academic medicine should be embarrassed. We've allowed our faculty to become tainted – rather than insisting they be the arbiters of

goodness and truth. We've allowed our training mission to serve a dual mission – true education and Pharma promotion.

## **Why do doctors interact with pharmaceutical reps?**

There are three reasons: 1) free food and perks, 2) doctors feel they deserve such gifts, and 3) reps often fill a perceived educational need.

The power of free food is not to be overlooked. Doctors and trainees work long hours and often skip lunch. In community hospitals, academic medical centers, Veterans Hospitals and clinics drug reps bring free food. They also hand out promotional material and shmooze with the doctors. Sometimes the drug reps give a 15-minute presentation. Companies often invite doctors to lavish restaurants to hear these presentations. Merck held such events often to promote their cox-2 inhibitor Vioxx and when asked about the cardiovascular dangers of the drug they downplayed any harm.

Doctors often perceive that they “deserve” these benefits since they are, after all, working long hard hours on behalf of their patients. Little thought is given to the huge cost that patients incur in paying for these meals and gifts that of course are part of the patients' high drug prices.

A recent study in the Annals of Internal Medicine (Feb 2005) explains why older physicians are less likely to deliver high-quality care. Medical advances occur frequently, and the explicit knowledge that physicians possess may easily become out of date. Therefore, although it is generally assumed that the tacit knowledge and skills accumulated by physicians during years of practice lead to superior clinical abilities, it has been shown that physicians with more experience may paradoxically be less likely to provide technically appropriate care. This applies most particularly to prescribing drugs. Doctors are aware that they quickly become out of date and seek easy ways to keep up to date. Pharma seeks to provide “a feel good” approach to learning about new medicines. Unfortunately, the information they provide is insufficient to educate a doctor. Comparisons between new and existing drugs are rare, and information is spun so as to make newer drugs sound far superior and safe. In fact, only a very small percentage of new drugs offer any substantial benefit over existing drugs.

## **Why are doctors willing to accept information from pharmaceutical reps?**

My research has shown that the courtship between Pharma and doctors in training starts early in medical school. Medical students are poor, overworked, and want to feel important. Drug companies sponsor mixers and “liver rounds” (aka parties), provides free pens, books, and medical equipment and even free prescription drugs all intended to appeal to the desires of medical students (relaxation, entitlement, and kindness). All of this is provided early and often through the medical school years without any expectation of directly impacting on prescribing; after all students are several steps removed from the actual writing of prescriptions – at least for the time being. However, the goal is to curry favor and prepare a futile soil for the future. Sandberg found that students given textbooks by pharmaceutical sales representatives are unlikely to remember the name of the

company or its products. However, the gift establishes habits, e.g. a willingness to receive gifts and the development of positive attitudes towards drug companies. This is the medical equivalent of feeding the bears in the National Parks. After just a few time of compassionate feeding the bears learn to keep coming back. In fact, they forget how to find food on their own. Doctors have become the health care system's educational "bears".

Once students graduate and they can prescribe drugs research shows promotional material is highly effective at altering prescribing patterns. Yet despite a large amount of research that documents a profound effect of promotion on doctor's prescribing habits doctors commonly deny that their prescribing decisions are in any way influenced by promotional material. Why? Because they want the lunches and they feel entitled.

### **What role has organized medicine and academic medicine taken to limit physician – Pharma interactions?**

In recent years the pharmaceutical industry's marketing tactics have come to the public's attention. Books by Angell, Kassirer, Avorn, and others have received national attention. Conflicts of interest at the NIH and other academic institutions have made national headlines. In response some organizations including the AMA and the ACP have introduced new guidelines to limit real and perceived conflicts of interest. In 2002 the Pharmaceutical Manufacturers Association reissued its own strengthened guidelines to cut back on bribery. But for the most part all these guidelines are window dressing intended to get the public and policy makers off their backs. Because these organizations have come to depend on industry money for their life blood there is little chance of meaningful change without strict new policies and federal oversight. Recall the example mention above involving the 2005 annual ACP meeting and its relationship with Pharma. On the one hand the organization issues strict rules about doctors relations with drug companies but on the other hand it promotes and court that same money. The same conflicts of interest exist at JAMA, the NEJM, UCLA, NYU, Harvard and nearly every other American medical school.

### **Does pharmaceutical promotion impact on doctor's prescribing behaviors?**

This is a difficult area to research but the answer is an unequivocal "yes". The outcome that is most important to measure is does the doctor write a prescription for a new product -- not whether or not she can answer some multiple choice questions. Most doctors are unaware of how much promotion they are exposed to. Surveys based on self-report are appropriate for finding out what people think is happening, or how they want to present themselves, but not what really happens in doctors offices or hospitals.

The outcomes that matter in terms of measuring promotion's effectiveness include 1) impact of promotion on the doctor's prescribing behavior, 2) impact of promotion on overall drug sales, and 3) physician's requests for additions to the pharmacy formulary.



A useful group of studies look at specific drugs and how they are promoted. From an industry perspective, a successful promotion results in positive changes in individual prescribing behavior. Bower and Burkett found that family physicians who reported relying less on drug sales representatives for information were likely to prescribe more generic drugs, as were residency trained doctors, and regular readers of weekly medical journals. Those who engaged in more appropriate and rational prescribing held more positive attitudes toward generics, and gave other indications of a less positive attitude towards the industry and promotion, than other doctors. Researcher found that the answer to a single question (are sales representatives a good sources of prescribing information about new drugs?) was most predictive of appropriate prescribing.

In summary, there is strong evidence that doctors who rely on promotion as a source of information about drugs, prescribe more drugs, prescribe less rationally, and prescribe new drugs earlier than other doctors. Two researchers (Orlowski and Wateska) looked at the impact of educational symposia on physician prescribing and their report is described this way:

*Using the hospital pharmacy inventory, they tracked the use of two drugs within one institution 22 months before and 17 months after each symposium about them. They also collected data on the national usage of these drugs, and informally interviewed the doctors who had gone to the symposia. Most of the doctors said that the symposia would not influence their prescribing, but some said that they might make them think of the drug more and the symposium might convince them of the benefits of the drug. Orlowski and Wateska found a dramatic and statistically highly significant increase in the use of the drugs in the hospital after the relevant symposia. These increases were not reflected in national data, and they did not seem to affect the hospital's use of alternative drugs. This study provides evidence firstly, that exposure to promotion increases prescribing, and secondly that it can do so whether or not those exposed consider themselves vulnerable to such influence.*

### **Does promotion have an impact on overall drug sales?**

Perhaps the most obvious answer to this question is “well, of course it does, why else would drug companies spend \$20 billion dollars!”

Some studies have tried to answer this question by observing prescribing changes before, during or after promotional activities. These studies are relatively simple and inexpensive and provide convincing evidence of the impact on promotion. Cleary looked at what happened when the level of promotion varied naturally over time, say when a sales representative was away on a sales training course. He examined trends in numbers of new prescriptions for three third-generation antibiotics in one hospital. He found that when the sales representative was away the numbers of new prescriptions for this product dropped. This did not happen to the other products studied, and there was no correlation between the pattern in this hospital or regional or national sales. Dieperink and

Drogemuller looked at one psychiatric medicine. They found that the reason for a dramatic increase in the use of an atypical antipsychotic agent in their Minneapolis hospital was a Grand Rounds presentation sponsored by the manufacturer of the product.

Of course the ideal way to find out about the impact of promotion on prescribing is to ask manufacturers to experimentally vary promotion over regions and times, monitor the effect of this and publish the results. There is no doubt that drug companies have done this many times over, but the information is proprietary. None-the-less, it seems clear that promotion leads to increased sales.

### **Are promotions aimed at doctors the only effective way to alter drug prescribing?**

No. Direct to consumer advertising (DTCA) is the fastest growing part of the advertising pie accounting for 20% (\$8 billion) of promotional activities (depending on how you count other activities). Like other promotional activities, the vast majority of advertised products are for new, expensive, “me-to” drugs that have little if any benefit over older more reliable drugs. The evidence that DTAs work is overwhelming. It works at defining disease, it works at setting patient expectations that they need a drug for their disease, it works at guilting doctors in to writing a prescription so as to maintain patient satisfaction or saving time, and most importantly, it works at selling drugs.

A growing number of studies have examined the effects of DTC advertising on consumer and clinician behavior, but few have directly addressed the issue of overprescribing. Last week we published in JAMA a randomized controlled trial using standardized patients (SPs) to address 3 research questions:

- (1) What are the effects of patients’ requests for a prescription on physician prescribing?
- (2) Does it make a difference whether patients’ requests are brand-specific (as might be prompted by viewing a DTC television advertisement) or general (as might arise from watching a television program about a health condition)?
- (3) What are the effects of brand-specific and general requests on 2 other health care indicators: referral and follow-up?

The results confirm that patients’ requests have a profound effect on physician prescribing, quality of medical care, and health care costs.

A major problem with DTCA is that there is no one at home guarding the hen’s and the fox is running around wild in the hen house. The FDA does not take their responsibility to monitor these medical messages seriously. It has less than 40 experts to review tens of thousands of print and electronic promotions. Even when the FDA does send out a disciplinary letter it is rarely effective at changing the manufacturers’ behavior. My research has shown that the public strongly believes that the FDA is monitoring and correcting drug advertisements to assure their accuracy in ways not done with other products.



## CONCLUSION

In conclusion, pharmaceutical promotions provide neither education nor enhance the quality of medical care – and there is evidence drugs ads may actually deter high quality care. Professional organizations of doctors, medical journals, and academic medicine have been bought out by the generous gifts provided by Pharma. Doctors have accepted drug “promotions” in lieu of bona fide education because it suits our desires (but not our needs) and it feeds our egos. The conflicts of interest are significant and obvious. Relying on drug companies for unbiased evaluations of their products makes no more sense than relying on vodka manufacturers to teach us about alcoholism. Pharma does not function in a free market and the playing field is not even. As such the government needs to assure a more equitable balance between the interests of shareholders and those of the public.

Doctors need to perceive that small gifts from drug company reps are not acceptable and profoundly influence prescribing choices. Few patients think *THEIR* doctor receives these promotional gifts; if they discovered this they report they would hold their doctor in lower regard. Perhaps this offers an opportunity to educate the public with the hope of altering physician behavior.

We know that government regulation of promotion is far more effective than industry self-regulation but only when the government (FDA) has teeth and isn’t afraid to use them. Journals can, but won’t, subject promotional material to the same sort of rigorous peer review as other educational material. Such a move risks offending advertisers and no journal has taken this responsible step -- all continue to publish misleading promotional information and claim it is not their responsibility to address accuracy or bias. In fact, journals actively promote themselves to Pharma as the most effective way to change doctor’s prescribing habits. Perhaps this is another good reason to require that all federally funded research be placed on PubMed Central with free public access and no commercial sponsorship.

It is difficult to think of any other area of commerce where false and misleading advertising and promotion can do as much damage as it can with pharmaceutical promotions.

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